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REMARKS

Claims 1 - 8 and 17 have been cancelled. After renumbering the remaining claims, Claims 1 - 9 remain in the application.

Applicant hereby requests further examination and reconsideration of the application, in view of the foregoing amendments.

Drawings

New drawings accompany this Reply, to overcome the objections set forth in the Office Action.

Section 102 Rejections

Claims 1, 9 and 16-18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Keeton. Claims 1 and 17 have been cancelled. Claim 9 has been amended and renumbered as claim 1. Claim 16 has been amended and renumbered as claim 8. Claim 18 has been amended and renumbered as claim 9. Each of these claims will be referred to henceforth by their new numbers.

Claim 1 (formerly claim 9) has been amended to limit the claimed device in two ways. First, the visually perceivable indicator is required "to warn against surgery on the body segment" to which the device is attached. Support for this limitation is found throughout the claims, and in particular in the last paragraph of page 3 of the Specification. Such a warning message is neither anticipated by the prior art nor rendered unobvious.

Keeton describes a surgical gown which may include a label directing a surgeon to

operate on a particular body part (see Keeton, column 2, lines 30-32). In contrast, the amended claims of the instant application expressly require an indicator which directs a surgeon NOT to operate on a particular body segment. This visual indicator provides a message which is significantly more likely to prevent wrong-site surgery than devices available in the prior art. For example, a patient may be scheduled for surgery on a right knee. If an error is made in the patient's chart, or if the surgeon incorrectly interprets the chart, the surgeon may prepare to operate on the patient's left knee. In this situation, if the patient has utilized Keeton's gown to identify the correct surgical site, the surgeon may never be aware of the Keeton-type label identifying the right knee. Since the surgeon intends to operate on the left knee, the surgeon is unlikely to even look at the right knee, and thus would be oblivious to a Keeton-type device. In contrast, use of the device claimed in claim 1, as amended, would result in a visually perceivable warning placed on the patient's left knee, with a warning against surgery on that body part. It can be appreciated that such a device is not anticipated by Keeton, and is more likely to be noticed by the surgeon than a Keeton-type device, and thus more likely to protect against wrong-site surgery.

Secondly, claim 1 (formerly claim 9) has been amended to require the claimed device to be attached to a body segment which is not to be affected by surgery, in a manner which permits the device to be removed after surgery. Support for this limitation is found throughout the specification, and in particular the next to the last paragraph of page 3.

Keeton teaches a gown which can be easily cut away from a patient, possibly removing any labels in the process (see Keeton, column 2, lines 29-30). In contrast, amended claim 1 requires a device which is removable after a surgical procedure has been concluded. In this manner, the warning against wrong-site surgery is kept in place both prior to and throughout surgery, in a manner unanticipated by Keeton.

Amended claim 8 (formerly claim 16) requires the use of a system which includes both

a device to identify a surgical site and a device to warn against surgery in an incorrect site. This system necessarily includes the device to warn against wrong-site surgery which is described and limited in the same terms as the device described in amended claim 1.

Amended claim 9 (formerly claim 18) requires the use of an applique, such as a temporary tattoo, which warns against wrong-site surgery. As with the device claimed in claim 1, the device of claim 9 is not anticipated nor made obvious by Keeton because it warns against surgery in a particular body segment and is not intended to be removed during a surgical procedure.

Section 103 Rejections

Claims 2 - 8 and 10 - 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Keeton in view of De Woskin. Claims 2 - 8 have been cancelled. Claims 10 - 15 have been amended by amendment of the claims on which they depend, and have been renumbered as claims 2 - 7. These claims will be referred to henceforth by their new numbers.

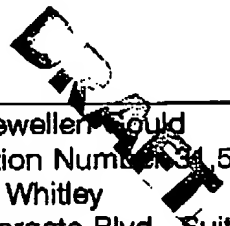
Claims 2 - 7 depend on Claim 1, and thus are subject to the limitations of claim 1. For reasons set forth above, it is submitted that claim 1 is not obvious given the limitations added to that claim by the instant Reply. Since those limitations are incorporated into claims 2 - 7, it is submitted that those claims are also non-obvious.

Additional References

Weaver discloses a warning device. It should be noted that the filing date of Weaver, February 15, 2000, is later in time than the filing date of the provisional application associated with the instant application, which was December 6, 1999.

In view of the above, it is submitted that the claims are in condition for allowance. Allowance of claims 1 - 9 at an early date is solicited.

Respectfully submitted,



Linda Flewellen Gould
Registration Number 34,515
Gould & Whitley
1665 Briargate Blvd., Suite 101
Colorado Springs, CO 80920
(719) 531-0994

I claim:

~~1. A pre-surgical safety, warning, notification, and/or alerting device or system comprising, in combination, an effectively shaped topical pre-printed or diagrammed warning strip.~~

~~2. A pre-surgical safety, warning, notification, and/or alerting device or system as described in Claim 1, including, in combination, an adhesive strip.~~

~~3. A pre-surgical safety warning, notification, and/or alerting device or system as described in Claim 1, wherein the notification agent is placed onto an adhesive surface.~~

~~4. A method for pre-surgically warning, notifying and/or alerting the surgical health care provider(s) that they are not at the intended surgical site, comprising the steps of:~~

~~forming a pre-surgical safety warning, notification, and/or alerting device or system in combination with an adhesive strip or surface and applying the safety, warning, notification, and/or alerting device or system topically at a location that alerts the surgical health care provider(s) that they are not at the intended surgical site.~~

~~5. A method as defined in Claim 4 wherein:~~

~~the pre-surgical safety, warning, notification, and/or alerting device or system is attached to an adhesive surface, and topically applying the adhesive surface at a location that alerts the surgical health care provider(s) that they are not at the intended surgical site.~~

~~6. A method as defined in Claim 5 further comprising:~~

~~leaving the pre-surgical safety, warning, notification, and or alerting device or system on the skin for a predetermined sufficient amount of time for complete, unambiguous pre-surgical identification of the impending surgical site as not being the intended surgical site.~~

~~7. A method as defined in Claim 6 further comprising an adhesive surface with an effective amount of a vinyl, PVC, cellulose, woven filament, fabric or other material of various sizes and shapes as a pre-printed surface.~~

~~8. A pre-surgical safety, warning, notification, and/or alerting device or system for topical application to the skin, comprising:~~

~~a pre-surgical safety, warning, notification, and/or alerting device or system, pre-printed and diagrammed; and an adhesive surface onto which the pre-surgical safety warning, notification, alerting device or system can be affixed for topical application to the skin and holding the pre-surgical safety, warning, notification, and/or alerting device or system in contact with a patient's skin at an unintended surgical site.~~

~~9.~~1. A pre-surgical alerting device comprising:

a. a strip suitable for placing on a body segment which is not to be affected by a surgical procedure, said strip having a superior side and inferior side,

b. visually perceivable indicator to warn against surgery on the body segment on said superior side, and

c. temporary attachment means for temporarily attaching said inferior side to the body segment in a manner which permits said strip to be removed after the surgical procedure. (amended)

~~10~~2. A pre-surgical alerting device according to claim 1, wherein said attachment means comprises an adhesive.

~~11~~3. A pre-surgical alerting device according to claim 1, wherein said strip is perforated to allow oxygen to diffuse to skin to which the strip is attached.

~~12~~4. A pre-surgical alerting device according to claim 1, wherein said visually perceivable indicator comprises the words "No Cut".

~~13~~5. A pre-surgical alerting device according to claim 2, further comprising peelable backing affixed to said inferior side to cover said adhesive when said device is not in use.

~~14~~6. A pre-surgical alerting device according to claim 1, further comprising a companion label suitable for detaching from said strip and for attaching to a patient's medical chart to indicate use of the alerting device.

~~15~~7. A pre-surgical alerting method, comprising the steps of:

a. applying a visually perceivable indicator to warn against surgery on a body segment to a superior side of a strip,

b. topically applying an inferior side of said strip to ~~a~~ the body segment which is not to be affected by a surgical procedure, and

~~c.~~ c. temporarily affixing said strip to said body segment in a manner which permits said strip to be removed after the surgical procedure. (amended)

~~16~~8. A pre-surgical alerting ~~device~~ system comprising:

a. ~~an alerting~~ notification strip suitable for placing on an involved body segment which is to be affected by a surgical procedure, said ~~alerting~~ notification strip having a superior side and inferior side,

b. visually perceivable indicator to indicate surgical site on said superior side of said ~~alerting~~ notification strip, ~~and~~

c. ~~c.~~ temporary attachment means for temporarily attaching said inferior side of said ~~alerting~~ notification strip to the involved body segment.

d. a warning strip suitable for placing on a body segment which is not to be affected by a surgical procedure, said warning strip having a superior side and inferior side,

e. visually perceivable indicator to warn against surgery on the body segment on said superior side, and

f. temporary attachment means for temporarily attaching said inferior side to the body segment in a manner which permits said warning strip to be removed after the surgical procedure. (amended)

~~17. A pre-surgical alerting device according to claim 16, further comprising:~~

~~d. a warning strip suitable for placing on a not-involved body segment which is not to be affected by a surgical procedure, said warning strip having a superior side and inferior side,~~

~~b. visually perceivable indicator on said superior side of said warning strip, and~~

~~c. temporary attachment means for temporarily attaching said inferior side of said warning strip to the not-involved body segment.~~

~~18~~9. A pre-surgical alerting method, comprising the steps of:

applying a skin-penetrative applique of a message warning against surgery ~~concerning an appropriate location for surgery~~ to a body segment which is not to be affected by surgery. (amended)

I claim:

1. A pre-surgical alerting device comprising:

a. a strip suitable for placing on a body segment which is not to be affected by a surgical procedure, said strip having a superior side and inferior side,

b. visually perceivable indicator to warn against surgery on the body segment on said superior side, and

c. temporary attachment means for temporarily attaching said inferior side to the body segment in a manner which permits said strip to be removed after the surgical procedure. (amended)

2. A pre-surgical alerting device according to claim 1, wherein said attachment means comprises an adhesive.

3. A pre-surgical alerting device according to claim 1, wherein said strip is perforated to allow oxygen to diffuse to skin to which the strip is attached.

4. A pre-surgical alerting device according to claim 1, wherein said visually perceivable indicator comprises the words "No Cut".

5. A pre-surgical alerting device according to claim 2, further comprising peelable backing affixed to said inferior side to cover said adhesive when said device is not in use.

6. A pre-surgical alerting device according to claim 1, further comprising a companion label suitable for detaching from said strip and for attaching to a patient's medical chart to indicate use of the alerting device.

7. A pre-surgical alerting method, comprising the steps of:

a. applying a visually perceivable indicator to warn against surgery on a body segment to a superior side of a strip,

b. topically applying an inferior side of said strip to the body segment which is not to be affected by a surgical procedure, and

c. temporarily affixing said strip to said body segment in a manner which

permits said strip to be removed after the surgical procedure. (amended)

8. A pre-surgical alerting system comprising:

a. a notification strip suitable for placing on an involved body segment which is to be affected by a surgical procedure, said notification strip having a superior side and inferior side,

b. visually perceivable indicator to indicate surgical site on said superior side of said notification strip,

c. temporary attachment means for temporarily attaching said inferior side of said notification strip to the involved body segment,

d. a warning strip suitable for placing on a body segment which is not to be affected by a surgical procedure, said warning strip having a superior side and inferior side,

e. visually perceivable indicator to warn against surgery on the body segment on said superior side, and

f. temporary attachment means for temporarily attaching said inferior side to the body segment in a manner which permits said warning strip to be removed after the surgical procedure. (amended)

9. A pre-surgical alerting method, comprising the steps of:

applying a skin-penetrative applique of a message warning against surgery to a body segment which is not to be affected by surgery. (amended)